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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/511,582 | 02/23/2000 | Jan Raa | CU-2140 TJK | 3180 |
| 26689 | 7590 | 06/02/2004 | EXAMINER | |
| WILDMAN, HARROLD, ALLEN & DIXON 225 WEST WACKER DRIVE CHICAGO, IL 60606 | | | WHITE, EVERETT NMN | |
| | | | ART UNIT | PAPER NUMBER |

1623

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/511,582

Applicant(s)

RAA ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 15, 2004 has been entered.
2. The amendment filed January 15, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 9-12 have been canceled;
 - (B) Claims 1-8 and 13-25 have been amended;
 - (C) Comments regarding Office Action have been provided drawn to:
 - (a) 112 2nd paragraph rejection, which has been withdrawn;
 - (a) 102(b) rejection, which has been withdrawn.
3. Claims 1-8 and 13-25 are pending in the case.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Election By Original Presentation

5. Newly submitted Claims 1-8 and 13-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally claimed invention is directed to a mucosal adjuvant composition that enhances the effect of medicinal substances administered onto mucosal surfaces, the mucosal adjuvant composition comprising a branched beta-1,3-glucan that contains beta-1,3-linked side chains anchored by a beta-1,6-linkage to the beta-1,3-linked chains. Applicants have amended the originally claimed invention to be drawn to a method comprising the steps of: providing an adjuvant comprising one or more beta-1,3 linkages and one or more beta-1,6 linkages that has been treated with an enzyme that selectively acts on the one or more beta-1,6 linkages, wherein the adjuvant does not induce

antibody production against itself; providing a vaccine; administering the vaccine to a mammal; and administering the adjuvant to the mammal.

The invention of the originally filed claims and the invention of the currently amended claims are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with another materially different product such as using a cyclodextrin compound or a cyclodextrin derivative or other compounds as an adjuvant with a vaccine.

See MPEP 706.07(h) Request for Continued Examination (RCE) Practice under section VII New Matter, wherein it is stated that as 35 U.S.C. 132(b) and 37 CFR 1.114 provide continued examination of an application (and not examination of a continuing application), the applicant cannot file an RCE to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined as a matter of right (i.e., applicant cannot switch inventions) (see 37 CFR 1.145).

Since Applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 1-8 and 13-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

6. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25, by setting forth the phrase "The composition of claim 17", is improperly dependent from Claim 17 since Claim 17 is directed to a method, which is withdrawn

from consideration. This inconsistent language and lack of antecedent basis renders Claim 25 indefinite.

7. Applicant's arguments with respect to Claim 25 have been considered but are moot in view of the new ground(s) of rejection.

Summary

8. Claim 25 is rejected; Claims 1-8 and 13-24 are withdrawn from consideration.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-

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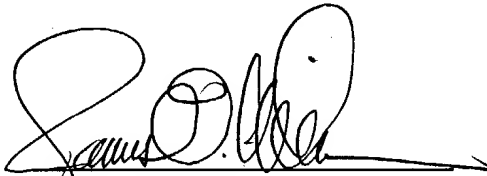
0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



E.White



James O. Wilson
Supervisory Primary Examiner
Technology Center 1600